

IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF OKLAHOMA

MARY A. CANTWELL, <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	
v.)	Case No. CIV-18-272-D
)	
SCOTT M. DE LA GARZA, M.D.,)	
<i>et al.</i> ,)	
)	
Defendants.)	

ORDER

Before the Court is Defendant Ulrich Medical USA, Inc.’s Amended Motion to Dismiss [Doc. No. 28], filed pursuant to Fed. R. Civ. P. 12(b)(6) and 9(b). Plaintiffs have filed a timely response [Doc. No. 33], and the movant has replied [Doc. No. 41]. Upon consideration, the Court rules on the Motion as follows.

Factual and Procedural Background

Plaintiffs originally brought suit in state court alleging that Plaintiff Mary Cantwell (“Mrs. Cantwell”) suffered personal injuries as a result of orthopedic surgery performed by Defendant Scott M. De La Garza in which a medical device designed, manufactured, and marketed by Defendant Ulrich Medical USA, Inc. (“Ulrich”) was implanted in her cervical spine. Mrs. Cantwell alleges that the device was approved by the United States Food and Drug Administration (“FDA”) for use only in the thoracolumbar spine and the unapproved use of the device for her surgery was not disclosed to her. Mrs. Cantwell asserts in her pleading various common law tort theories of recovery; as to Ulrich, she

asserts claims of conspiracy to commit fraud, conspiracy to commit battery, and negligence per se.¹ In support of her negligence claim, Mrs. Cantwell alleges that her injuries were caused by violations of federal statutes regulating medical devices, namely, the “Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, via the Medical Devices Amendments of 1976.” *See* Pet. [Doc. No. 1-2], ¶¶ 37-38, 41. Plaintiff William Cantwell (“Mr. Cantwell”) asserts claims for loss of consortium based on his wife’s alleged injuries.

Defendant SSM Health Care of Oklahoma, Inc. (“SSM”) removed the case to federal court with the consent of other defendants based on federal question jurisdiction under 28 U.S.C. § 1331 and issues arising under the FDCA. *See* Notice of Removal [Doc. No. 1], ¶ 3. The parties subsequently stipulated to Plaintiffs’ voluntary dismissal of SSM. *See* Stip. Dismissal [Doc. No. 44]. Defendant Scott M. De La. Garza, M.D. has answered.

By its Motion, Ulrich seeks dismissal from the case on the ground that Plaintiffs’ petition fails to state a plausible claim against it under federal pleading standards because: 1) Mrs. Cantwell’s battery claim is time barred by a one-year statute of limitations; 2) her fraud claim is not pleaded with the particularity required by Rule 9(b); 3) she has not alleged sufficient facts to establish a civil conspiracy; 4) her negligence per se claim fails because she has not identified a statute that was allegedly violated; and 5) Mr. Cantwell’s claims are derivative of his wife’s claims and fail for the same reasons.²

¹ Because Plaintiffs do not allege any direct contact with a representative of Ulrich before or during Mrs. Cantwell’s surgery, the Court assumes their theory of Ulrich’s liability is based on its alleged participation in a civil conspiracy with other defendants, as discussed *infra*.

² Ulrich also asserts that any claim based on a failure to warn or provide information to Mrs. Cantwell is barred by the learned intermediary doctrine. Although this doctrine may provide

In addition to arguments directed at Plaintiffs' tort theories, Ulrich "adopts and incorporates by reference the federal preemption argument raised by Defendant SSM . . . in its Motion to Dismiss dated April 2, 2018 [Doc. No. 9] and which was granted by the Court in its Order dated April 27, 2018 [Doc. No. 23]." *See* Ulrich's Mot. Dismiss at 4.³ Plaintiffs responded to Ulrich's Motion by purporting to adopt by reference their response to SSM's motion, in anticipation of a future filing. *See* Pls.' Resp. Br. at 10-11. However, Plaintiffs later dismissed SSM before the deadline for their response, and no brief was filed.⁴ Under these circumstances, where Ulrich has simply adopted another party's argument and Plaintiffs have made no response, the Court finds any issue of federal preemption has been inadequately briefed. Ulrich may raise this defense in a proper manner at an appropriate time.

Standard of Decision

"To survive a motion to dismiss [under Rule 12(b)(6)], a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); *see Robbins v. Oklahoma*, 519 F.3d 1242, 1247 (10th

an affirmative defense to liability under certain circumstances, Ulrich fails to sufficiently explain its application to the claims asserted in this case, and thus, the Court does not reach this issue.

³ In a footnote, Ulrich "reserves its right to fully brief federal preemption as a defense that completely bars Plaintiffs' claims later in the litigation." *Id.* at 4 n.1; *see* Reply Br. at 8 n.4. To date, Ulrich has not presented any preemption argument of its own.

⁴ On June 4, 2018, the Court vacated the April 27 Order and directed Plaintiffs to respond to SSM's motion within 7 days. *See* Order Granting Plfs.' Am. Mot. Vacate [Doc. No. 43]. On June 11, 2018, Plaintiffs voluntarily dismissed SSM. *See* Stipulation of Dismissal [Doc. No. 44].

Cir. 2008). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678. In assessing plausibility, a court should first disregard conclusory allegations and “next consider the factual allegations in [the] complaint to determine if they plausibly suggest an entitlement to relief.” *Id.* at 681. The question to be decided is “whether the complaint sufficiently alleges facts supporting all the elements necessary to establish an entitlement to relief under the legal theory proposed.” *Lane v. Simon*, 495 F.3d 1182, 1186 (10th Cir. 2007) (internal quotation omitted). However, “‘if the allegations [of a complaint] show that relief is barred by the applicable statutes of limitations, the complaint is subject to dismissal for failure to state a claim.’” *Vasquez Arroyo v. Starks*, 589 F.3d 1091, 1096-97 (10th Cir. 2009) (quoting *Jones v. Bock*, 549 U.S. 199, 215 (2007)).

Allegations of fraud are governed by the heightened pleading requirements of Rule 9(b), which provides:

In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.

Fed. R. Civ. P. 9(b). “At a minimum, Rule 9(b) requires that a plaintiff set forth the ‘who, what, when, where and how’ of the alleged fraud, and must set forth the time, place, and contents of the false representation, the identity of the party making the false statements and the consequences thereof.” *United States ex rel. Sikkenga v. Regence Bluecross Blueshield*, 472 F.3d 702, 726-27 (10th Cir. 2006) (internal quotations omitted); *see Toone*

v. Wells Fargo Bank, N.A., 716 F.3d 516, 522 (10th Cir. 2010); *Tal v. Hogan*, 453 F.3d 1244, 1263 (10th Cir. 2006). To determine if factual allegations satisfy Rule 9(b), the Court reviews only the text of a complaint; matters outside the pleading may not be considered unless permitted by Rule 12(b)(6). *See Toone*, 716 F.3d at 521; *Sikkenga*, 472 F.3d at 726; *Tal*, 453 F.3d at 1264 & n.24. The Court “accept[s] as true all well-pleaded facts, as distinguished from conclusory allegations, and view[s] those facts in the light most favorable to the non-moving party.” *Sikkenga*, 472 F.3d at 726.

Discussion

1. Timeliness of Mrs. Cantwell’s Battery Claim

Plaintiffs allege that Defendants’ battery of Mrs. Cantwell occurred on February 29, 2016, when Dr. De La Garza performed her surgery. This case was filed almost two years later on February 28, 2018. A civil action for battery must be brought within one year after the cause of action accrues. *See Okla. Stat. tit. 12, § 95(A)(4)*. Ulrich contends this statute applies to Mrs. Cantwell’s conspiracy-to-commit-battery claim because “civil conspiracy must be based on a valid underlying tort.” *See Ulrich’s Mot. at 2* (emphasis omitted), 7 (quotation omitted). Ulrich thus asserts that any battery claim against it is untimely.

Plaintiffs’ sole response to Ulrich’s challenge to the timeliness of Mrs. Cantwell’s battery claim is to argue that their action was filed within the two-year statute of limitations for healthcare claims. *See Pls.’ Resp. Br. at 12-13*. Plaintiffs rely on a special statute that applies to actions “against any physician, health care provider or hospital licensed under the laws of this state.” *See Okla. Stat. tit. 76, § 18*. Plaintiffs point to no allegations of their pleading that would bring Ulrich within the class of defendants covered by this statute.

Therefore, the Court finds that any battery claim that could otherwise be brought against Ulrich is time barred and must be dismissed.

2. Mrs. Cantwell's Fraud Claim Against Ulrich

Plaintiffs assert that their pleading adequately states a fraud claim under a theory of fraudulent nondisclosure or concealment, also known as constructive fraud. *See* Pls.' Resp. Br. at 14-15 (citing *Varn v. Maloney*, 516 P.2d 1328, 1332 (Okla. 1973), and Okla. Uniform Jury Instruction No. 18.2); *see also Howell v. Texaco, Inc.*, 112 P.3d 1154, 1161 (Okla. 2004) ("Constructive fraud is the concealment of a material fact by one who has a duty to disclose."). Plaintiffs argue that "no defendant gave [them] any information" about the allegedly unapproved and "experimental" use of Ulrich's device for Mrs. Cantwell's surgery or about an alleged "financial relationship between the defendants." *See* Pls.' Resp. Br. at 13-14. According to Plaintiffs, they have "adequately alleged a set of facts that by failing to apprise them of the true nature of Mrs. Cantwell's surgery, [Defendants] perpetrated fraud through omission." *Id.* at 15.

"To recover under a theory of constructive fraud, [a plaintiff] must prove:

- (1) That the defendant owed plaintiff a duty of full disclosure. This duty could be part of a general fiduciary duty owed by the defendant to the plaintiff. This duty could also arise, even though it might not exist in the first instance, once a defendant voluntarily chooses to speak to plaintiff about a particular subject matter;
 - (2) That the defendant misstated a fact or failed to disclose a fact to plaintiff;
 - (3) That the defendant's misstatement or omission was material;
 - (4) That plaintiff relied on defendant's material misstatement or omission;
- and

(5) That plaintiff suffered damages as a result of defendant’s material misstatement or omission.”

Specialty Beverages, L.L.C. v. Pabst Brewing Co., 537 F.3d 1165, 1180-81 (10th Cir. 2008) (internal quotation and omitted) (applying Oklahoma law).

Plaintiffs argue generally that their pleading contains sufficient facts to support this theory of fraud, but their argument contains no reference to or citation of any particular allegations. Upon examination of the state-court petition, the Court finds the only factual allegations to satisfy the “who, what, when, where and how” requirements of Rule 9(b) are ones that identify Dr. De La Garza as a person who met with Mrs. Cantwell before her surgery and failed to advise her that Ulrich’s device was only approved for use in the thoracolumbar spine. *See* Pet. ¶ 10. Plaintiffs do not identify any facts that would establish Ulrich owed Mrs. Cantwell a duty of disclosure or withheld information from her. The Court therefore finds that Plaintiffs have failed to state a fraud claim against Ulrich.

3. Civil Conspiracy

The allegations of Plaintiffs’ pleading suggest, and their arguments regarding civil conspiracy make clear, that their theory of Ulrich’s liability for fraud is based on the alleged existence of a conspiracy among Defendants to withhold information from Mrs. Cantwell. *See* Pls.’ Resp. Br. at 16 (“These defendants acted in concert to accomplish an experimental surgery to their own pecuniary benefit, by omission, fraud and deceit.”).

“A civil conspiracy consists of a combination of two or more persons to do an unlawful act, or to do a lawful act by unlawful means.” *Brock v. Thompson*, 948 P.2d 279, 294 (Okla. 1997). Under Oklahoma law, “[i]n essence, a civil conspiracy claim enlarges

the pool of potential defendants from whom a plaintiff may recover for an underlying tort.” *Id.* at 294 n.66. “The essential elements are: (1) two or more persons; (2) an object to be accomplished; (3) a meeting of minds on the object or course of action; (4) one or more unlawful, overt acts; and (5) damages as the proximate result.” *Schovanec v. Archdiocese of Okla. City*, 188 P.3d 158, 175 (Okla. 2008) (internal quotation omitted).

Plaintiffs point to four paragraphs of their pleading that allegedly contain sufficient factual allegations to satisfy these elements and show a conspiracy to commit fraud. *See* Pls.’ Resp. Br. at 16. The Court finds in those paragraphs, however, no facts to support a reasonable inference that two or more persons – presumably the remaining defendants, Dr. De La Garza and Ulrich – reached a meeting of the minds to defraud Mrs. Cantwell. The only alleged connection between these defendants, other than Ulrich’s provision of the medical device and the presence of an Ulrich employee during the surgery, is that they had a “financial relationship” under which “Dr. De La Garza has received compensation from Ulrich.” *See* Pet. ¶¶ 10-11. Assuming the truth of this fact, it provides an insufficient basis to conclude that Ulrich and Dr. De La Garza had agreed as part of their relationship to deceive and “coerce [Mrs. Cantwell] into undergoing experimental cervical spine surgery with an unapproved/uncleared corpectomy cage.” *See id.* ¶ 14. Plaintiffs’ conclusory allegations that “Defendants conspired to coerce and/or deceive [Mrs. Cantwell] to undergo a dangerous surgery she would not have consented to had she been informed of all the facts” (*id.* ¶ 19) are insufficient to support a conspiracy to defraud Mrs. Cantwell.

In short, the Court finds that Plaintiffs’ pleading fails to state a plausible claim against Ulrich of conspiracy to commit fraud.

4. Negligence Per Se

Plaintiffs assert that the factual allegations of their pleading are sufficient to state a tort claim of negligence per se even though “the Petition does not reference specific sections of the Act.” *See* Pls.’ Resp. Br. at 18. According to Plaintiffs, their pleading is sufficient because “the allegations are very clear with respect to the unlawful actions” and “the pleading of easily identified statutory requirements by responsibility rather than by citation is sufficient.” *Id.* at 18, 19. Plaintiffs argue that “the FDCA and the corresponding FDA regulations prohibit manufacturer promotion of off-label uses” of medical devices (*id.* at 19), and they include in their argument citations of federal statutes and regulations regarding product labeling and branding. *Id.* at 18-19.

The Oklahoma Supreme Court was specifically asked to consider a negligence claim in the context of federal regulation of medical devices in *Howard v. Zimmer*, 299 P.3d 463 (Okla. 2013). The supreme court explained: “The negligence per se doctrine is employed to substitute statutory standards for parallel common law, reasonable care duties.” *Id.* at 467. “To establish negligence per se, the plaintiff must demonstrate the claimed injury was caused by the violation [of a statute], and was of the type intended to be prevented by the statute . . . [and] the injured party [was] one of the class intended to be protected by the statute.” *Id.* at 467 (footnote omitted). If these elements are shown, the doctrine of “[l]iability per se enables plaintiffs to establish as a matter of law that the defendant’s conduct constituted a breach of duty in a negligence action, so that only causation and damages need be proven.” *Id.* (footnote omitted).

In *Howard*, the plaintiff asserted a negligence claim based on the violation of a federal regulation, 21 C.F.R. § 820.70(h). Answering a question certified by the Tenth Circuit, the Oklahoma Supreme Court decided that a violation of an administrative regulation could support a claim of negligence per se, and that a parallel state-law claim premised on the violation of FDCA regulations should be permitted. *See Howard*, 299 P.3d at 468, 472-73. The court said nothing to suggest, however, that a plaintiff wishing to bring such a claim could proceed without identifying the statute or regulation allegedly violated, and thus the duty allegedly breached, by the defendant's conduct.

Plaintiffs' assertion that they need not plead the violation of a particular statute or regulation to state a claim of negligence per se is unsupported by any citation of authority. Further, Plaintiffs' discussion of possible FDCA statutes and regulations at issue highlights the necessity of identifying a provision allegedly violated and the conduct at issue. As observed by Ulrich (Reply Br. at 7-8, discussing *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1341-42 (10th Cir. 2015)), and implicitly acknowledged by Plaintiffs (Resp. Br. at 19, also discussing *Caplinger*), such identification is particularly important in the area of medical devices, where a state-law negligence claim must survive the FDCA's provision of a federal preemption defense. To the extent Plaintiffs' citations of federal regulations in their brief are intended to supply the missing element, the Court declines to allow Plaintiffs to amend their pleading in this way.⁵

⁵ The Court's contextual approach to Plaintiffs' claim of negligence per se is consistent with the Supreme Court's guidance in *Iqbal*, 556 U.S. Ct. at 679, that determining the sufficiency of a complaint is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *See also Kan. Penn Gaming, LLC v. Collins*, 656 F.3d 1210,

Absent the identification of a federal statute or regulation that provides the duty allegedly violated by Ulrich, the Court finds that Plaintiffs have failed to state a plausible claim of negligence per se.

5. Mr. Cantwell's Claims

Plaintiffs do not dispute that Mr. Cantwell's claims are derivative claims that depend on a viable tort claim stated by his wife. *See* Pls.' Resp. Br. at 21. Therefore, because Mrs. Cantwell has failed to state a claim for relief, Plaintiffs' pleading also fails to state a claim on which Mr. Cantwell can obtain relief.

6. Leave to Amend

Anticipating a finding that their state-court petition may not satisfy federal pleading standards, Plaintiffs alternatively assert that they should be allowed to amend their pleading to cure any deficiency. *See* Pls.' Resp. Br. at 22. Plaintiffs have not filed a motion to amend under Rule 15(a)(2), nor have they complied with the requirement of LCvR15.1 to provide a proposed pleading. However, because Plaintiffs should have an opportunity to amend their pleading if they can state a claim consistent with Fed. R. Civ. P. 11, the Court finds that the dismissal should be granted with leave to amend.

Conclusion

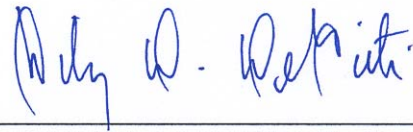
For these reasons, the Court finds that Plaintiffs have failed to state any claim against Ulrich on which relief can be granted. The Court further finds, however, that

1215 (10th Cir. 2011) ("The nature and specificity of the allegations required to state a plausible claim will vary based on context."); *Robbins*, 519 F.3d at 1248 ("degree of specificity necessary to establish plausibility and fair notice . . . depends on context").

Plaintiffs' action against Ulrich should be dismissed with leave to file an amended pleading.

IT IS THEREFORE ORDERED that Defendant Ulrich Medical USA, Inc.'s Amended Motion to Dismiss [Doc. No. 28] is GRANTED. Plaintiffs' action against Defendant Ulrich Medical USA, Inc. is dismissed without prejudice to the filing of an amended complaint within 14 days from the date of this Order.

IT IS SO ORDERED this 13th day of November, 2018.



TIMOTHY D. DEGIUSTI
UNITED STATES DISTRICT JUDGE